K002449

DEC 22 2000

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

1. Submitter's Name: BIOTEQUE CORPORATION
   Address: Suite 402, 4th Fl, No. 136, Sec.3,Jen-Ai Road, Taipei, R.O.C.
   Phone: 886-2-2708-6716
   Fax: 886-2-2707-6610
   Contact: Mr. William Lee (General Manager)

2. Device Name
   Trade Name: **BIOTEQ® I.V. (INTRAVENOUS) SET**
   Common Name: **IV ADMINISTRATION SET**
   Classification name: **SET, ADMINISTRATION, INTRAVASCULAR**

3. Classification: Class II

4. Predicate Device: **EXEL I.V. ADMINISTRATION SET (K963659) marketed by EXEL INTL.**

5. Device Description: **BIOTEQ® I.V. (INTRAVENOUS) SET** consist of the following major components:
   the spike with drip-chamber, the PVC Tube, the Plastic Roller(Clamp) , the Luer connector(Needle Hub), the Protective cap for Luer(Needle Hub Protector).
   These major components assembled together as **I.V. (Intravenous) Set** for use to administer medical fluids from a container to patient's vascuiar system through a inserted into a vein.

6. Intended Use: **BIOTEQ® I.V. (INTRAVENOUS) SET** is used to administer medical fluids from a container to patient's vascular system through a catheter inserted into a vein.

7. Performance Summary: In terms of Physical specification, Chemical specification, Biological specification & Sterilization Specification, the device conforms to applicable standards included ISO 10993 Series & USP XXIII series Biological Specification, ISO 11607-1, ISO 11135, USP Pyrogenic standards & related standards----etc.

8. Conclusions:

The **BIOTEQ® I.V. (INTRAVENOUS) SET** have the same intended use and similar technological characteristics as the **EXEL I.V. ADMINISTRATION SET (K963659) marketed by EXEL INTL.**. Moreover, bench testing contained in this submission demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the **BIOTEQ® I.V. (INTRAVENOUS) SET** is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 22 2000

Ms. Jennifer Chen
Bioteque Corporation
900 N. Switzer Canyon Drive #142
Flagstaff, Arizona 86001

Re: K002449
Trade Name: BIOTEQ® I.V. (Intravenous) Set
Regulatory Class: II
Product Code: FPA
Dated: October 7, 2000
Received: October 11, 2000

Dear Ms. Chen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic

Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) NUMBER (IF KNOWN): K002449

DEVICE NAME: **BIOTEQ® I.V. (INTRAVENOUS) SET**
BIOTEQUE CORPORATION

INDICATIONS FOR USE:

BIOTEQ® I.V. (INTRAVENOUS) SET is used to administer medical fluids from a container to patient's vascular system through a catheter inserted into a vein.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002449